# Selenia® Dimensions® and 3Dimensions™ Synthesized 2D Software Physician Labeling


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## 1.1 Manufacturer Contact Information

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## 1.2 Prescription Use Statement

℞ Only United States federal law restricts this device to use by, or on the order of, a physician.

## 1.3 Intended Use

### 1.3.1 Selenia Dimensions

The Hologic® Selenia® Dimensions® system generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The Selenia Dimensions (2D or 3D) system is intended for use in the same clinical applications as a 2D mammography system for screening mammograms. Specifically, the Selenia Dimensions system can be used to generate 2D digital mammograms and 3D mammograms. Each screening examination may consist of:

- a 2D FFDM image set, or
- a 2D and 3D image set, where the 2D image can be either a FFDM or a 2D image generated from the 3D image set

The Selenia Dimensions system may also be used for additional diagnostic workup of the breast.

**Note**
In Canada and Singapore, Tomosynthesis is not approved for screening, and must be used in conjunction with a 2D image (either a FFDM image or 2D image generated from the 3D image set).

### 1.3.2 3Dimensions

℞ Only Caution: Federal law restricts this device to sale by or on the order of a physician.

The Hologic® 3Dimensions™ system is indicated to generate digital mammographic images that can be used for screening and diagnosis of breast cancer. The 3Dimensions (2D or 3D) system is intended for use in the same clinical applications as a 2D mammography system for screening mammograms. Specifically, the 3Dimensions system can be used to generate 2D digital mammograms and 3D mammograms. Each screening examination may consist of:

- a 2D FFDM image set

  - OR -

- a 2D and 3D image set, where the 2D image can be either an FFDM or a 2D image generated from the 3D image set

The 3Dimensions system may also be used for additional diagnostic workup of the breast.

**Note**
In Canada and Singapore, Tomosynthesis is not approved for screening, and must be used in conjunction with a 2D image (either a FFDM image or 2D image generated from the 3D image set).

## 1.4 Definition of Hologic Synthesized 2D Product

C-View: A licensed Hologic feature where a standard digital mammography (DM) image is generated from data acquired during a standard resolution breast tomosynthesis (BT) scan. The standard resolution tomosynthesis image and the C-View image have a pixel resolution of approximately 100 microns.

Intelligent 2D: A licensed Hologic feature where a high-resolution digital mammography (DM) image is generated from data acquired during a high resolution breast tomosynthesis (BT) scan. The high resolution tomosynthesis image and the Intelligent 2D image have a pixel resolution of 70 microns.

## 1.5 Potential Adverse Effects of Mammography Systems on Health

Below is a list of the potential adverse effects (such as complications) associated with the use of the device (these risks are the same as for other screen-film or digital mammography systems):

- Excessive breast compression
- Excessive x-ray exposure
- Electric shock
- Infection
- Skin irritation, abrasions, or puncture wounds

No serious adverse events were reported for the patients enrolled in the clinical study.

## 1.6 Major Warnings / Cautions / Contraindications

**Note**
Refer to the *User Guide* for more information about warnings and precautions.

### 1.6.1 Warnings

**Warning:**
**Do not make a clinical decision or diagnosis from a synthesized 2D image without reviewing the accompanying tomosynthesis image set.**

Use a synthesized 2D image in the same way you would use conventional digital mammography (2D) when performing a screening study employing tomosynthesis.

- While reviewing a synthesized 2D image for items or areas of interest, compare to a prior digital mammogram (2D) if priors exist and then review the related tomosynthesis images carefully.
- Carefully examine the entire tomosynthesis image set before making a clinical decision.

**Warning:**
**The appearance of a synthesized 2D image may differ from that of a conventional digital mammography (2D) image, just as 2D film and digital mammography (2D) images from different vendors may look different.**

Users should ensure they are adequately trained and are familiar with the appearance of a synthesized 2D image before using them in conjunction with tomosynthesis image sets.

### 1.6.2 Contraindications

There are no known contraindications.

## 1.7 Synthesized 2D Software

Synthesized 2D software uses image data available from a breast tomosynthesis acquisition to generate one digital mammogram (2D) per breast tomosynthesis acquisition. The synthesized 2D image is created without the need for an additional digital mammography exposure. The synthesized 2D image is designed to appear similar to, and serve the same purpose as, a digital mammogram (2D) when used as part of a screening study employing tomosynthesis. The synthesized 2D image is interpreted in combination with a breast tomosynthesis image set and is not intended to be used without the accompanying breast tomosynthesis images to make a clinical decision or diagnosis.

## 1.8 Clinical Study Summary

**Note**
The combination of a synthesized 2D image and tomosynthesis images will be referred to as synthesized 2D plus 3D.

### 1.8.1 C-View Results

Hologic compared the performance of C-View plus 3D breast imaging to conventional full field digital mammography (2D) imaging in a reader study with 15 radiologists. The reader study included 302 cases of which 77 were cancer cases. The study was a fully crossed reader study with a 1 month delay between reading sessions. All radiologists read all cases in both modes (2D and C-View plus 3D). The study cases included images from women with both fatty and dense breasts. Women with a prior excisional biopsy, an internal breast marker, breast implants or breasts too large to be imaged in a single compression were excluded from the study. The exclusions were related to the reader study design and additional data on the excluded subjects was collected to support the clinical use of C-View and 3D in these instances. This reader study was designed to evaluate the use of C-View plus 3D imaging in a screening mode compared to conventional 2D screening.

The primary endpoint of this study was to demonstrate that diagnostic accuracy using C-View plus 3D was non-inferior to 2D imaging. Diagnostic accuracy was measured using the area under the Receiver Operating Characteristic (ROC) curve. There were also two secondary endpoints: 1) demonstrate that the diagnostic accuracy of C-View plus 3D was non-inferior to 2D for women with dense breast tissue (BIRADS breast density of 3 or 4) and 2) demonstrate that the non-cancer recall rate for C-View plus 3D was non-inferior to 2D. All endpoints for the reader study were met and in addition to showing non-inferiority, the study demonstrated superior diagnostic accuracy for all cases (primary endpoint) and superior (lower) non-cancer recall rate for C-View plus 3D compared to 2D.

The average ROC curves for the reader study are shown in Figure 1. C-View plus 3D has a superior ROC curve compared to 2D alone. An improved ROC curve is one that is closer to the upper left of the axes. A perfect imaging method would have a true positive fraction of 1 (100%) and a false positive fraction of 0 (0%). These curves also allow estimation of the potential gains in sensitivity and specificity that may be achieved by using C-View plus 3D compared to 2D.

*Figure 1: Average ROC Curves for the 15 Readers: All Cases*

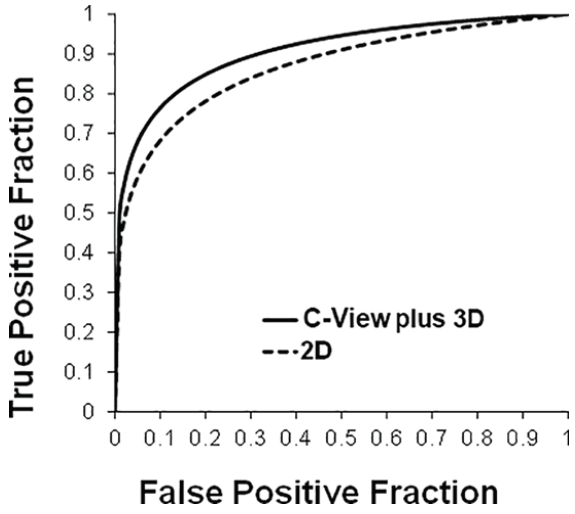
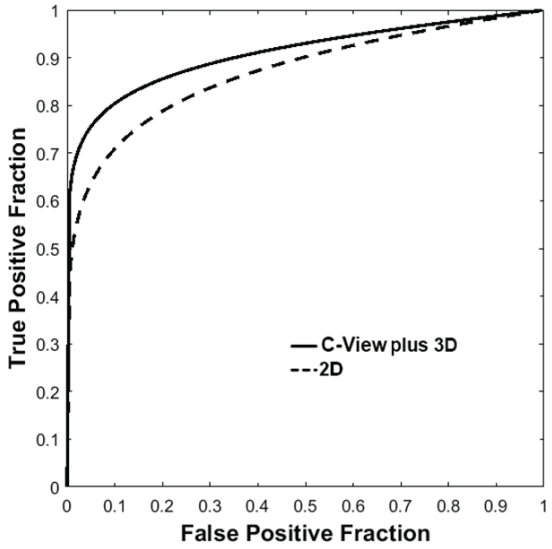



*Figure 2: Average ROC Curves for the 15 Readers: Dense Breast Cases*




The clinical study results summarized above demonstrate that there is a significant benefit in using C-View plus 3D imaging for routine screening mammography. Diagnostic accuracy was shown to increase while non-cancer recall rate was shown to decrease with C-View plus 3D compared to 2D imaging. In particular, C-View plus 3D demonstrated superior performance, as measured using area under the ROC curve, compared to 2D imaging in women with dense breasts. The non-cancer recall rate was also shown to decrease with C-View plus 3D compared to 2D imaging in women with dense breasts. In summary, C-View plus 3D demonstrated superior performance compared to 2D imaging, both in all breast densities, and also in the subgroup of dense breasts.

## 1.9 Intelligent 2D Results

A preference study was conducted to compare the image quality for the Intelligent 2D synthesized 2D images to C-View synthesized 2D images. Seven MQSA-qualified radiologists reviewed 119 images that were processed with both Intelligent 2D and C-View software. The cases represented a range of breast densities and mammographic findings. The radiologists had experience reading tomosynthesis images. Readers included in the evaluation study had a range of backgrounds and prior experience, as described in the following table::

| Reader number | Practice type | Average Annual Mammography Interpretation Volume (Personal) | Breast Imaging Fellowship | Years Active | Years of Tomosynthesis Experience | Prior CView Experience |
|---|---|---|---|---|---|---|
| 1 | Academic | 3500+ | Yes | 2009- present | 4 | Yes |
| 2 | Community | 6000+ | No | 1998-present | 5 | yes |
| 3 | Community | 2000 | No | 1983-present | 8 | Yes |
| 4 | Academic | 5000+ | Yes | 2004-present | 7 | Yes |
| 5 | Community | 6000+ | No | 1993-present | 7 | Yes |
| 6 | Community | 5000+ | Yes | 1994-Present | 7 | Yes |
| 7 | Community | 2000 | No | 1982-present | 7 | Yes |

The cases represented a range of breast densities and mammographic findings. The distribution of case findings is shown in the following table:

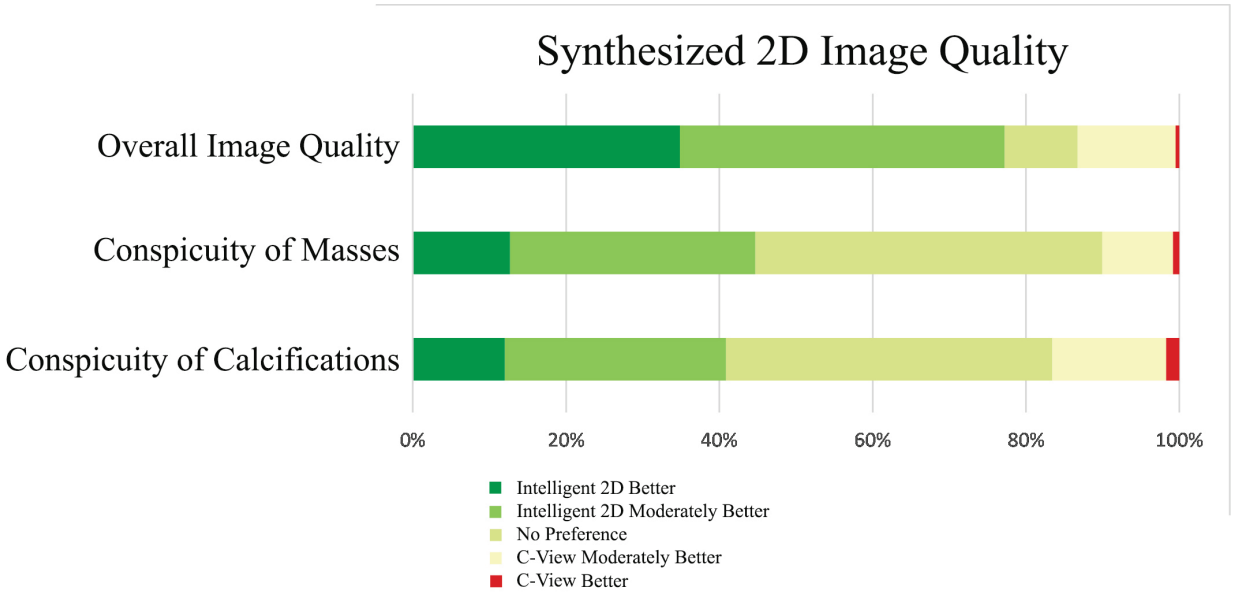
| | Malignant | Benign | Total |
|---|---|---|---|
| Mass Lesion | 35 | 27 | 62 |
| Calc Lesion | 18 | 24 | 42 |
| Mass and Calcification Lesion | 7 | 3 | 10 |
| Negative | | | 5 |
| Grand Total | | | 119 |

In the reading session, the radiologists were asked to compare Overall Image Quality (including assessment of noise and artifacts), Conspicuity of Masses, and Conspicuity of Calcifications of two images, one of which was the Intelligent 2D image and the other the C-View image. The images were blinded and occurred in random order on the left and right workstation monitors. The radiologist scored their preference as to which image was superior, moderately better, or if there was no preference.

The results obtained from 833 readings (seven readers, 119 images) are shown in Figure 3. Overall Image Quality of the Intelligent 2D images was found to be equivalent to C-

View images. Conspicuity of Masses and Conspicuity of Calcifications were found to be equivalent to C-View images. . In summary, 87% of readings for Overall Image Quality, 90% of readings involving masses, and 83% of readings involving calcifications were rated equivalent or better for Intelligent 2D images as compared to C-View images. There was some variability amongst the radiologists (one radiologist preferred C-View to Intelligent 2D on the majority of the images) but, on average, a very high percentage of readings were either equivalent or better for the Intelligent 2D images.

*Figure 3: Synthesized 2D Image Quality Preferences*
*7 readers, 119 images. Overall Image Quality had no missing values across 833 possible responses. Conspicuity of Masses had 3 missing values across 504 possible responses (7 readers, 72 cases with masses). Conspicuity of Calcifications had 16 missing values across 364 possible responses (7 readers, 52 cases with calcifications).*




## 1.10 Dose Comparison

| | Standard Resolution | High Resolution |
|---|---|---|
| **Mode** | **Dose (mGy)[1]** | **Dose (mGy)[1]** |
| 2D | 1.20 | 1.20 |
| 3D | 1.45 | 1.45 |
| Synthesized 2D + 3D | 1.45 | 1.45 |
| 2D and 3D | 2.65 | 2.65 |
| Screen-Film[2] | 1.90 | 1.90 |

[1] 4.2cm compressed breast with composition of 50% glandularity
[2] Bloomquist AK, Yaffe MJ, Pisano ED et. al. Quality control for digital mammography in the ACRIN DMIST trial: part I. Med Phys 2006; 33: 719-736.